Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEAN P. KINET
and JAREMA P. KOCHAN

Appeal No. 1997-2122
Application 08/310,902

ON BRIEF

Before WILLIAM F. SMITH, Administrative Patent Judge, and McKELVEY, Senior Administrative Patent Judge, and ADAMS, Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claim 3, the only claim pending in the application. Claim 3 reads as follows:

3. A polypeptide comprising the amino acid sequence corresponding to the α-subunit of the human FcERI essentially free of the β- and γ-subunits of the human FcERI.

The references relied upon by the examiner are:

Kumar et al. (Kumar), "Gel Filtration In 6M Guanidine Hydrochloride of the α-Subunit (And its Fragments) of the Receptor for Immunoglobulin E," Molecular Immunology, Vol. 19, No. 12, pp. 1561-567 (1982)

Kishi, "A New Leukemia Cell Line With Philadelphia Chromosome Characterized As Basophil Precursors," Leukemia Research, Vol. 9, No. 3, pp. 381-90 (1985)

A reference relied upon by this merits panel is:

Conrad et al. (Conrad), "The Interaction Of Human And Rodent IgE With The Human Basophil IgE Receptor," The Journal of Immunology, Vol. 130, No. 1, pp. 327-33 (1983)

Claim 3 stands rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the examiner relies upon Kumar and Kishi. We reverse and enter a new ground of rejection under 37 CFR § 1.196(b).

DISCUSSION

As seen, claim 3 is directed to a polypeptide which comprises the amino acid sequence corresponding to the α- subunit of the human FcERI essentially free of the β- and γ-subunits of the human FcERI. The examiner relies upon Kumar for its disclosure of a procedure for isolating the α-subunit of the rat FcERI. The examiner relies upon Kishi for its disclosure of the human cell line KU812. As set forth in the paragraph bridging pages 4-5 of the Examiner's Answer, the examiner's position is that it would have been obvious to one of ordinary skill in the art to have "isolated a human FcERI α-subunit like the rat FcERI α-subunit of Kumar et al. by substituting the KU812 cells of Kishi… for the rat basophils that were employed in the purification process of Kumar et al."

In order for a claimed invention to be unpatentable under the statute, the subject matter of that claim must have been obvious to a person of ordinary skill in the art at the time of the invention under review. As is apparent, the examiner's theory of the case presupposes that at the time of the present invention one of ordinary skill in the art understood that KU812 cells express the human FcERI. Otherwise, why would one of ordinary skill in the art have the needed reason, suggestion or motivation to combine the references? However, in responding to appellants' arguments at page 5 of the Examiner's Answer, the examiner states "it is conceded that this fact was not known prior to the making

of the invention." By conceding that workers in this field did not know at the time of the present invention that KU812 expressed FcERI, the examiner conceded his case. Absent evidence that those of ordinary skill in the art at the time of the present invention understood that KU812 did express the receptor of interest, it is not apparent on what basis it can reasonably be concluded that it would have been obvious to use KU812 cells in the process of Kumar.

The examiner's rejection is reversed.

NEW GROUND OF REJECTION UNDER 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection.

Claim 3 is rejected under 35 U.S.C. § 102(b)/103 on the basis of Conrad.

As set forth above, claim 3 is directed to a polypeptide which comprises the amino acid sequence corresponding to the α-subunit of the human FcERI which is essentially free of the β- and γ- subunits of the human FcERI. As explained in the background portion of the specification, FcERI is a receptor having high infinity for human IgE.

Conrad isolated the human IgE receptor and studied its cross-reactivity with mouse and rat IgE. The IgE receptor of Conrad was isolated using the procedure described in the left-hand column of page 328. As explained, the receptor was isolated by repetitive affinity chromatography on hIgE-Sepharose.

In the first full paragraph of the right-hand column of 331, Conrad indicates that at the time of that work the surface accessible IgE receptors found on rat basophilic leukemia cells and rat mast cells were found to be associated with a second polypeptide termed "β component." Conrad explains that the surface labeling used in their study would not be expected to detect a human β equivalent and that the identification of a human β equivalent "probably awaits the development of a human cell line bearing the high-affinity IgE receptor." It is of interest to note the discussion in the paragraph bridging pages 331-32 of Conrad that the cells used in that study may have two distinct types of IgE receptors, i.e., one which binds both human IgE and rodent IgE with high-affinity and a second which showed high-affinity binding only for human IgE.

Conrad describes the polypeptide which is characterized as a human IgE receptor which binds human IgE with high-affinity. It is not clear from Conrad whether that isolated polypeptide is "essentially free of the β- and γ-subunits of the human FcERI" as required by claim 3 on appeal. Under these circumstances, it is reasonable to shift the burden to appellants to establish whether the procedures described in Conrad for isolating the IgE receptor result in obtention of the α-subunit to the essential exclusion of the β- and γ- subunits. As set forth in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

TIME PERIOD FOR RESPONSE

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (2000). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review." 37 CFR § 1.196(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED; 37 CFR § 1.196(b)

William F. Smith Administrative Patent Judge	)
Fred E. McKelvey, Senior Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

William D. Noonan, M.D.
KLARQUIST, SPARKMAN, CAMPBELL, LEIGH
& WHINSTON
One World Trade Center
121 S. W. Salmon Street, 16th Floor
Portland, OR 97204-2988

WFS/cam